REMARKS

Claims 31, 34-48, 50, 53-59, and 61 were pending. By virtue of this response, claims 31, 46, 48, and 50 are amended, claims 62-65 are newly added, and claims 41-45, 57-58 and 61 are canceled. Therefore, claims 31, 34-40, 46-48, 50, 53-56, 59, and 62-65 are presently pending. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. All amendments are fully supported by the specification and claims, as originally filed. No new matter is added.

I. Claim Rejections Under 35 USC §112

Claims 31 stands rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. The omitted structural cooperative relationships are: how the circuit means is cooperating with the electrodes and where the electrical signal is coming from. Also missing is processor or similar means to create the map based on the electrical signals to bridge the gap between the circuit and display.

Claim 31 has been amended to recite, in part:

> a wound dressing including a two-dimensional array of test electrodes . . .
>
> a circuit **electrically coupled to the two-dimensional array of test electrodes**, the circuit for measuring an electrical characteristic of tissue underlying each test electrode, said circuit comprising:
>
> **a switching device** for **selecting successive test electrodes**, and
>
> **an analyser** for **passing an electrical alternating current between each selected test electrode** and at least one further electrode . . .
>
> a display device **electrically coupled to the analyzer**, the display device for presenting a visual map **generated using analyser circuitry** . . .

(Emphasis added.) See, for example, Figure 9 and ¶¶ 0073-0075 for support.

Claim 31, as amended, specifies that the circuit is electrically coupled to the two-dimensional array of electrodes. Claim 31 further recites a switching device for selecting successive

test electrodes (of the two-dimensional array) and an analyser for passing current to said electrodes. Thus, Applicant submits that the structural and cooperative relationship between the array of test electrodes and the circuit is sufficiently defined.

Claim 31 also specifies that the display device is electrically coupled to the analyzer, thus defining the cooperative and structural relationship between the display and circuit elements.

Finally, claim 31 recites that the visual map is generated using analyser circuitry. Thus, one of skill understands that the analyser circuitry bridges the gap between the circuit and the display.

Applicant submits that claim 31, as amended, satisfies 35 U.S.C. 112, second paragraph. Applicant respectfully requests that the rejection of claim 31 on this ground be withdrawn.

II. Claim Rejections Under 35 USC §103

Claims 31, 34-48, 50, 53-59 and 61 stand rejected under 35 U.S.C. 103 as purportedly being unpatentable over Bloom et al. (U.S. Patent No. 6,963,772, "Bloom" hereinafter).

Claim 31 has been amended to recite, in part:

> a circuit electrically coupled to the two-dimensional array of test electrodes, the circuit for measuring an electrical characteristic of the tissue underlying each test electrode, said circuit comprising:
>
> a switching device for selecting successive test electrodes, and
>
> an analyser for passing an electrical alternating current between each selected [**first**] test electrode and at least one further [**second**] electrode applied to the skin at a location away from the wound,
>
> said analyser further calculating the electrical characteristic of the tissue under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference [**third**] electrode adjacent to the currently selected test electrode . . .

(Bracketed text added.) See, for example, Fig. 9, ¶¶ 0073-0078 for support. This is referred to herein as the "three-electrode" measuring configuration, i.e., using a test electrode, a further electrode and a reference electrode.

This claim is distinguished from Bloom in two significant ways: (1) Bloom doesn't expressly teach or suggest presenting a visual map indicating the size and shape of the wound (this is admitted by the Examiner) and (2) Bloom does not disclose the use of a three-electrode configuration as specified in the passages added to claim 1.

1. The references cannot be combined to teach "presenting a visual map"

The Examiner alleges that Kenan et al. (U.S. Patent No. 6,788,966, "Kenan" hereinafter) teaches an electrode array device for measuring skin impedance and displaying skin lesions in a visual map indicating size and shape (Kenan at Figures 8, 9A), and further that it would have been obvious in view of Kenan to provide visual maps of the wound in Bloom in order to visibly track the healing process.

Kenan uses a matrix of electrodes imbedded in a probe. Kenan uses a two-electrode configuration with the second electrode (common for all the electrodes located above a tumor) placed remotely on the body. (Kenan at 6:45-49.)

In order to overcome the electrode-skin interface impedance problem inherent with the 2-electrode configuration, Kenan uses electrodes in the matrix which are in the form of points pushed into the skin, thus bypassing the electrode-skin impedance (which is precisely what the present invention seeks to measure). (*See, e.g.*, Kenan at 6:8-14 and 11:45-56.)

Admittedly, Kenan can produce maps of the impedances measured between each of his matrix electrodes and the common second electrode. However, as the electrode-skin impedances of Kenan matrix electrodes have been effectively removed, the measured impedances (and corresponding maps produced) are those of the underlying tissues/tumors sandwiched between the probe's matrix electrodes and the common electrode.

Additionally, Bloom does not measure under each individual electrode using a large electrode array (as asserted by the Examiner). Bloom does not locate a matrix of electrodes above a wound, it does not remove the electrode-skin impedance contributions, nor does it locate a common

second electrode on a remote site. It cannot do as Kenan has done. It measures something (undefined) across a wound using a two-electrode configuration to monitor subcutaneous fluid under the wound surface. This data, whatever it might be, cannot be used to create a map of the wound and size. It would be a bit like saying an investigation of presence of water under the region of Paris is the same as taking an aerial photograph of the size and shape of the city.

While Bloom and Kenan both use an array of electrodes, the two references measure different things using different electrode configurations. Applicant submits that the references could not reasonably be combined to arrive at the subject matter of the invention.

2. Bloom does not suggest or disclose a three-electrode configuration

In Bloom, electrical current is applied to a pair of sensors (electrical leads), which are placed on a portion of the body. (Bloom abstract.) A first lead supplies the current and a second lead acts as a current sink. (*Id.* at 4:47-52.) Electrical measurements are taken between these two leads. There is no (third) reference electrode, adjacent to a selected test electrode that is used, in conjunction with the other two electrodes. Furthermore, Bloom does not disclose or suggest calculating an electrical characteristic as a function of the voltage difference between a selected test electrode and a (third) reference electrode, as recited in claim 31.

In contrast, claim 31 recites a three-electrode configuration. Specifically, claim 31 recites, "an analyser for passing an electrical alternating current between each selected [first] test electrode and at least one further [second] electrode applied to the skin at a location away from the wound." (Bracketed text added.) Furthermore, claim 31 requires a third electrode used for calculating an electrical characteristic. Specifically, claim 31 recites calculating an electrical characteristic of the tissue as a function of a voltage difference measured "between the currently selected test electrode and at least one [third] reference electrode, adjacent to the currently selected test electrode." (Bracketed text added.)

In the three-electrode configuration of the present application (see, e.g., Figure 6 of the present application), a test electrode 10 is applied onto the area of skin of interest. Current is applied through the test electrode and a "back" electrode 34 ("further electrode" in claim 1) located at some remote site. A reference electrode 22 is applied to the skin close to the test electrode. The voltage between the test electrode and the nearby reference electrode is measured. Substantially no current can flow through the reference electrode-skin interface, or through the intervening dermal tissue. No voltage is therefore dropped across these impedances (Fig. 6, Z_2 and Z_{dermis}) and hence the measured voltage dropped between the test electrode 10 and the reference electrode 22 is due substantially to the applied current flowing through the impedance (Z_1) of the test electrode-skin interface. Knowing the applied current and the measured voltage, one can readily deduce the impedance (Z_1).

The three electrode configuration, therefore, provides information concerning the impedance of the skin immediately below the test electrode, without contributions from the impedances of the reference electrode-skin interface, the indifferent electrode-skin interface or the intervening tissues (the last, in fact, being the subject of Bloom's specification).

The three-electrode configuration is used in the present invention as it enables the measurement (and thus mapping) of the skin or tissues immediately underlying the individual electrodes of the matrix incorporated into the wound dressing.

The passages in Bloom cited by the Examiner at 9:8-20, 9:39-50 and 4:47-65 do not disclose a three-electrode configuration. At most, the electrodes in Bloom are said to "straddle the wound" in what appears to be a two-electrode configuration.

The Examiner also refers to Figures 2D and 4 of Bloom, and asserts that they disclose a three-electrode arrangement. However, the references 38 are explicitly identified as the locations for the electrical leads 10, and do not denote a separate (third) electrode. In reference to Figs. 2A-2G, Bloom states, "[w]ith impedance sensors, where two sensor locations are provided, each location corresponds to the end of an electrical lead 4." (Bloom at 8:22-25.) Additionally, Figure 4

of Bloom clearly shows a two-electrode device with electrodes in positions straddling the wound, clearly using a 2-electrode configuration to monitor subcutaneous fluid under the wound surface.

Individual electrodes (or "sensor members" Bloom 4:40-41) are denoted 10 by Bloom (Fig 1A and Fig 4) and two of these form what Bloom calls an "impedance sensor." (Bloom at 4:38-39; 15:4-6; Fig 1A.) Bloom does not talk about "individual test electrodes," as, given their two-electrode configuration, electrodes or "sensor members" must be used in pairs. (*See, e.g.*, Bloom at 4:49-52; 8:30-32; Figure 1A; Fig 2A; Fig 4; 8:22-25.) In particular Bloom states:

> In operation, AC current or voltage is applied through the leads via a predefined spectrum of frequencies or selected single frequencies as needed. For impedance sensor variations of the invention, there will always be at least two electrodes, since one needs a source and sink for current (in this case, alternating current).

(Bloom at 4:47-52, emphasis added.) Bloom does not suggest or disclose a third sensor/electrode that is not used to either sink or source current applied to the tissue. Further, one would understand the "at least two electrodes" disclosed in Bloom to mean multiple pairs of electrodes, each pair providing a current sink or a current source.

For at least these reasons, Applicant asserts that Bloom in view of other art does not render obvious the rejected claims. Applicants respectfully request that the rejection of these claims be withdrawn and the claims allowed.

A detailed discussion of each obviousness rejection made by the Examiner is included below.

III. Claim Rejections Under 35 USC §103, Bloom

Claims 31, 34-36, 39-44, 46-47 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom.

Claim 31 has been amended to recite, in part:

> a circuit electrically coupled to the two-dimensional array of test electrodes, the circuit for measuring an electrical characteristic of the tissue underlying each test electrode, said circuit comprising:
>
> a switching device for selecting successive test electrodes, and
>
> an analyser for passing an electrical alternating current between each selected test electrode and at least one further electrode applied to the skin at a location away from the wound,
>
> said analyser further calculating the electrical characteristic of the tissue under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference electrode adjacent to the currently selected test electrode . . .

This is described above as the "three-electrode" measuring configuration (i.e., using a test electrode, a further electrode and a reference electrode).

In Bloom, electrical current is applied to a pair of sensors (electrical leads), which are placed on a portion of the body. (Bloom abstract.) A first lead supplies the current and a second lead acts as a current sink. (*Id.* at 4:47-52.) In Bloom, electrical measurements are taken between the two leads. In Bloom, there is no (third) reference electrode, adjacent to a selected test electrode. Furthermore, Bloom does not disclose or suggest calculating an electrical characteristic as a function of the voltage difference between a selected test electrode and a (third) reference electrode, as recited in claim 31.

In contrast, the three-electrode configuration of claim 31 recites "an analyser for passing an electrical alternating current between each selected [first] test electrode and at least one further [second] electrode applied to the skin at a location away from the wound." (Bracketed text added.) Furthermore, claim 31 requires a third electrode used for calculating an electrical characteristic. Specifically, claim 31 recites calculating an electrical characteristic of the tissue as a function of a voltage difference measured "between the currently selected test electrode and at least one [third] reference electrode, adjacent to the currently selected test electrode." (Bracketed text added.)

In rejecting the claims, the Examiner refers to Figures 2D and 4 as disclosing a three-electrode arrangement. However, the sensors 38 are explicitly identified as the locations for the electrode pairs 10, and do not denote separate (third) electrodes. Figure 4 also shows a two-electrode device with electrodes in positions straddling the wound.

Additionally, Bloom does not teach or render obvious "presenting a visual map indicating the size and shape of the wound," as recited in claim 31. As described above, Bloom measures across a wound using a two-electrode configuration to monitor subcutaneous fluid under the wound surface. Bloom does not disclose or suggest adapting the two-electrode configuration to include a two-dimensional array of electrodes to create a map of the wound's size and shape.

Because Bloom does not disclose a three-electrode configuration and does not suggest creating a map of the wound's size and shape, Bloom does not render obvious claim 31. Furthermore, claims 34-36, 39-40, and 46-47 are not obvious for at least the reason that they depend from allowable claim 35.

Claims 41-44 and 61 have been canceled mooting the rejection of those claims.

Accordingly, Applicant respectfully requests that the rejection of claims 31, 34-36, 39-40, and 46-47 be withdrawn and the claims allowed.

IV. Claim Rejections Under 35 USC §103, Bloom in view of Pearlman

Claims 37 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claim 31 above, and further in view of Pearlman (U.S. Patent No. 6,308,097, "Pearlman" hereinafter).

In general, Pearlman discloses methods of detecting deep tissue abnormalities (e.g., breast cancer tumors) by sensing electrical characteristics of the deep tissue. (*See, e.g.*, Pearlman at 19:37-39.) Applicant submits that Pearlman does not disclose or suggest a three-electrode configuration and, therefore, does not remedy the deficiencies in the Bloom disclosure.

Applicant submits that claims 37 and 48 are patentable for at least the reason that they depend from allowable claim 31. Accordingly, Applicant respectfully requests that the rejection of claims 37 and 48 be withdrawn and the claims allowed.

V. Claim Rejections Under 35 USC §103, Bloom in view of Kenan

Claims 50-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom in view of Kenan.

In general, Kenan uses a matrix of electrodes imbedded in a probe. In particular, Kenan uses a two-electrode configuration with the second electrode (common for all the electrodes located above a tumor) placed remotely on the body. (*See, e.g.*, Kenan at 6:45-49.) In order to overcome the electrode-skin interface impedance problem inherent with the 2-electrode configuration, Kenan uses electrodes in the matrix which are in the form of points pushed into the skin, thus bypassing the electrode-skin impedance (which is precisely what the present invention seeks to measure).

Applicant submits that Kenan does not disclose or suggest a three-electrode configuration and, therefore, does not remedy the deficiencies in the Bloom disclosure. Because neither Bloom nor Kenan, alone or in combination, teach all of the limitations of claim 50, the references do not render claim 50 obvious.

Claims 57-58 have been canceled, mooting the rejection of those claims.

Applicant submits that claims 53-56 and 59 are patentable for at least the reason that they depend from allowable claim 50. Accordingly, Applicant respectfully requests that the rejection of claims 50, 53-56, and 59 be withdrawn and the claims allowed.

VI. Claim Rejections Under 35 USC §103, Bloom in view of Cudahy

Claims 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claims 31 and 41 above, and further in view of Cudahy et al. (U.S. Patent No. 5,184,620).

Applicant submits that Cudahy does not disclose or suggest a three-electrode configuration and, therefore, does not remedy the deficiencies in the Bloom disclosure. Claim 45 has been canceled, mooting the rejection of that claim.

Applicant submits that claim 38 is patentable for at least the reason that it depends from allowable claim 31. Accordingly, Applicant respectfully requests that the rejection of claim 38 be withdrawn and the claim allowed.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 595552000100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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